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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,500	03/29/2002	Nobuo Hanai	249-255	9448

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EXAMINER	
BLANCHARD, DAVID J	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,500	HANAI ET AL.	
	Examiner	Art Unit	
	David J. Blanchard	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,15,16,22-24,32,36,37,40,41,48,50,51,57,58 and 62-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48* is/are allowed.

6)☒ Claim(s) *1,15,16,22-24,32,36,37,40,41,50,51,58 and 62-64* is/are rejected.

7)☒ Claim(s) *57 and 65* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/15/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 February 2006 has been entered.

2. Claims 2-14, 17-21, 25-31, 33-35, 38-39, 42-47, 49, 52-56 and 59-61 are cancelled (see item no. 3 below regarding claim 33).

Claims 1, 15-16, 22-24, 32, 36-37, 40-41, 48, 50-51, 57-58 and 62 have been amended.

Claims 63-65 have been added.

3. Applicant's attention is directed to claim 33, which has been omitted from the amendment filed 2/22/2006. Applciant is reminded that "The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given." See MPEP 714(C). In view of the omission of claim 33, claim 33 is being interpreted as canceled by the amendment filed 2/22/2006. In the interest of compact prosecution, Applicant should include the status identifier for claim 33 in response to this Office Action.

4. Claims 1, 15-16, 22-24, 32, 36-37, 40-41, 48, 50-51, 57-58 and 62-65 are pending and under examination.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. This Office Action contains New Grounds of Rejections.

Objections/Rejections Withdrawn

7. The rejection of claims 10-13, 20-23, 26-28, 30-31 and 36-41 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "derivative" is withdrawn in view of the amendments to the claims and the cancellation of others in the response filed 2/22/2006.

8. The rejection of claim 24 under 35 U.S.C. 112, first paragraph for lack of enablement is withdrawn in view of the amendments to the claim.

9. The rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under 35 U.S.C. 103(a) as being unpatentable over Shitara et al [a] in view of Queen et al and Nakamura et al is withdrawn in view of the amendments to the claims.

10. The rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under 35 U.S.C. 103(a) as being unpatentable over Shitara et al [b] in view of Queen et al and Nakamura et al is withdrawn in view of the amendments to the claims.

11. The rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under 35 U.S.C. 103(a) as being unpatentable over Shitara et al [c] in view of Queen et al and Nakamura et al is withdrawn in view of the amendments to the claims.

12. The rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable

over claims 1-4 of US Patent No.6,437,098 B1 in view of Queen et al and Nakamura et al is withdrawn in view of the amendments to the claims.

13. The rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of US Patent No. 5,750,078 in view of Shitara et al [c] and Queen et al and Nakamura et al is withdrawn in view of the amendments to the claims.

14. The rejection of claims 1-2, 6, 9-13, 15-16, 24, 26-28, 36-39 and 50-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of US Patent No. 6,495,666 B2 in view of Shitara et al [c] and Queen et al and Nakamura et al is withdrawn in view of the amendments to the claims.

15. The rejection of claims 10-13, 20-23, 26-28, 30-31 and 36-41 under 35 U.S.C. 112, second paragraph, as lacking antecedent basis for the limitation "The derivative" is withdrawn in view of the amendments to the claims and cancellation of others.

16. The rejection of claims 50, 55-58 and 62 under 35 U.S.C. 112, second paragraph as lacking antecedent basis for the limitation "The human CDR grafted antibody" is withdrawn in view of the amendments to the claims and cancellation of others.

17. The rejection of claim 24 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "a peptide comprising CDR1, CDR2 and CDR3 of the H chain V region and CDR1, CDR2 and CDR3 of the L chain V region." Is withdrawn in view of the amendments to the claim.

18. The rejection of claim 48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for introducing new matter into the claims is withdrawn in view of applicant's arguments and amendments to the claim.

19. The rejection of claim 48 is rejected under 35 U.S.C. 112, first paragraph, for lack of enablement (item no. 35 of the previous Office Action) is withdrawn in view of applicant's arguments and amendments to the claim.

Response to Arguments

20. The rejection of claim 32 under 35 U.S.C. 112, second paragraph as being indefinite in the recitation of "derivative" is maintained.

The response filed 2/22/2006 states that the objected to term has been amended to advance prosecution. This has been fully considered but is not found persuasive. While it appears applicant intended to amend claim 32, the claim still recites the term "derivative", and the rejection is maintained for reasons already of record.

21. The rejection of claim 32 under 35 U.S.C. 112, second paragraph, for lack of antecedent basis for the limitation "The derivative" is maintained.

The response filed 2/22/2006 states that this rejection has been obviated by the amendments to the claims. This has been fully considered but is not found persuasive. Claim 32 still recites the term "The derivative", which lacks antecedent basis in base claim 1.

New Grounds of Objections/Rejections

Specification

22. The disclosure is objected to because of the following informalities:

a. The specification at pg. 8, lines 17-19 discloses that FERM BP-6790 produces an anti-GD3 CDR grafted antibody as well as its fusion to human IL-2 (hIL-2) (see pg. 8, line 35 to pg. 9, line 3), which appears to be a typo in view of pg. 16, line 1 of the specification, which discloses that the anti-GD3 CDR grafted antibody (i.e., KM8871) fused to hIL-2 is produced by the transformant deposited as FERM BP-6791.

b. The specification is objected to for improper arrangement. As provided in 37 CFR 1.77(b), the specification of a utility application should include a Background of the Invention followed by a Brief Summary of the Invention followed by a Brief Description of the Drawings and a Detailed Description of the Invention. See MPEP 608.01(a). The instant specification does not contain a "Brief Summary of the Invention" followed by a "Brief description of the Drawings" and it appears applicant's "Disclosure of the Invention", beginning at pg. 8 is the Detailed Description of the Invention, including the disclosed examples. Thus, a "Brief Summary of the Invention" should be added at pg. 8, followed by the Brief Description of the Drawings, followed by a Detailed Description of the Invention (i.e., presently under the heading "Disclosure of the Invention"). Applicant's Brief Description of the Figures is noted on pages 46-55 of the specification.

c. The use of the trademark Super Script™ has been noted in this application (see pg. 29, line 25). It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicant's cooperation is requested in reviewing and

correcting any additional trademarks of which applicant may become aware in the specification.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

d. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Objections

23. Claims 22 and 65 are objected to because of the following informalities:

Claim 22 recites "the H chain V region having the amino acid sequences represented by SEQ ID NO:9", which is gramatically incorrect. Amending the term "sequences" to "sequence" would overcome this objection.

Claim 65 is objected to as containing a hyphen before the term "humanized".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

24. Claims 1, 15-16, 22-24, 32, 36-37, 40-41, 50-51, 58, 62 and 63-64 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1, 15-16, 23-24, 36-37, 40, 50-51, 58, 62 and 63-64 are indefinite in reciting that the claimed humanized antibody comprises the heavy chain CDRs of SEQ ID Nos:3-5 and the light chain CDRs of SEQ ID Nos:6-8 and the heavy chain variable region of SEQ ID NO:9 or the light chain variable region of SEQ ID NO:54, making it unclear what the claimed humanized antibody comprises. Are the CDRs in addition to the heavy or light chain variable regions of SEQ ID Nos:9 and 54, does the humanized antibody comprise two different heavy chain variable regions or two different light chain variable regions? Further, in view of dependent clais 23, 40, 58 and 62, it is unclear what the transfromant KM8871 produces. Does transformant KM8871 produce a humanized antibody comprising the heavy and light chain CDRs of SEQ ID Nos:3-8 or comprising the heavy and light chain CDRs of SEQ ID Nos:3-8 and the heavy chain variable region of SEQ ID NO:9 or the light chain variable region of SEQ ID NO:54 as claimed (e.g., claims 1 and 63) or does transformant KM8871 produce the humanized antibody comprising the heavy chain variable region of SEQ ID NO:9 and the light chain variable region of SEQ ID NO:54 or is some other humanized antibody produced by trasnfromant KM8871 or is the humanized antibody-IL-2 conjuagte produced by the transformant KM8871, particularly in view of the specification, which assigns the same deposit number, FERM BP-6790, as producing the anti-GD3 CDR-grafted antibody and the anti-GD3 CDR-grafted antibody conjuagted to human IL-2 (hIL-2) (see specification pg, 8, lines 17-19, pg. 8, line 35 to pg. 9, line 3).

b. Claim 41 is indeifnite in the recitation "the H chain V region having the amino acid sequence represented by SEQ ID NO:53" because SEQ ID NO:53 is 582 amino acids in length. Those of skill in the art recognize that antibody variable regions are about 110 amino acids in length as evidenced by Alberts et al (Molecular Biology of the Cell, 3rd Ed. pp. 1216-1217, 1994). Thus it is not clear what is contemplated by the phrase "the H chain V region having the amino acid sequence represented by SEQ ID NO:53", where SEQ ID NO:53 is 582 amino acids in length.

c. Claims 1, 15-16, 22-24 and 32 are indefinite in the recitation "a protein or a low molecular weight agent" in claim 1. At pg. 25, the specification discloses that the antibodies of the invention are produced by "conjugating a radioisotope, a protein, a low molecular weight agent or the like..." to the antibody. The specification at pp. 25-26 discloses various well-known therapeutic moieties that may be used to produce the presently claimed antibody conjugate, however, it is not clear what is contemplated by the phrase "or the like" and the claims do not state the function, which is to be achieved by the claimed "protein or a low molecular weight agent". Thus, when read in light of the specification, one of ordinary skill in the art could not ascribe a discrete and identifiable class of proteins or low molecular weight agents to the phrase "a protein or a low molecular weight agent". As written, one of ordinary skill in the art would not be reasonable apprised of the metes and bounds of the claimed invention.

Amending claim 1 to recite "conjugated with a therapeutic agent...", consistent with applicant's disclosed utility would overcome this rejection. Applicant is reminded

that such an amendment would also require amending claim 36 (i.e., "protein" changed to therapeutic agent), consistent with claim 1.

25. Claims 1, 15-16, 24, 36-37, 50-51 and 63-64 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 2/22/2006 has introduced NEW MATTER into the claims. As presently amended claim 1 and newly added claim 63 recite GD3-specific humanized antibodies or fragments thereof (conjugated or not) comprising the heavy chain CDRs of SEQ ID Nos:3-5 and the light chain CDRs of SEQ ID Nos:6-8 and the heavy chain variable region of SEQ ID NO:9 or the light chain variable region of SEQ ID NO:54. The as filed disclsoure does not provide adequate written support for a GD3-specific humanized antibody or fragment thereof and conjugates thereof wherein the humanized antibody or fragment thereof binds GD3 and comprises the heavy chain variable region CDRs of SEQ ID Nos:3-5 and the light chain variable region CDRs of SEQ ID Nos:6-8 and a heavy chain variable region comprising SEQ ID NO:9 or a light chain variable region comprising SEQ ID NO:54 as presently amended or newly added. The as-filed disclsoure appears to provide adeqaute wirtten support for humanized antibodies comprising the heavy chain CDRs of SEQ ID Nos:3-5 and the light chain CDRs of SEQ ID Nos:6-8 (although not free of the prior art of record) as well as humanized antibodies

comprising the heavy chain of SEQ ID NO:9 and/or the light chain of SEQ ID NO:54 and conjuagtes thereof. Again, although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in presently amended claim 1 and newly added claim 63, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the present claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Conclusion

26. Claims 57 and 65 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

27. Claim 48 is free of the prior art. The prior art does not teach or fairly suggest the humanized anti-GD3 antibody comprising the heavy and light chain variable region sequences recited in the claim.

28. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to Tony Parks for Art Unit 1643 whose telephone number is 571-272-0543.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827